

## REMARKS

Claims 22-26, 28-33, 36-50, and 52-92 are pending. Of these, claims 66-92 have been withdrawn from consideration. Claims 22-26, 28-33, 36-50, 52-65 and 74-87 are rejected. Claims 22, 31, 39, 42 and 66 have been amended. Claims 88 and 89 have been canceled without prejudice or disclaimer. New claims 93 and 94 have been added. Reconsideration of the rejection is respectfully requested in view of the following remarks.

### **Election by Original Presentation**

The Action states that newly submitted claims 88-92 are directed to an invention that is independent or distinct from the invention originally claimed. Applicants partially traverse this position. Applicants respectfully submit that independent claim 90 does not require a second implantable device. Applicants respectfully submit that independent claim 90 reads on the elected Invention Group II (implantable device) and the elected species of the compressed fibrous matrix being in the form of a sheet. Accordingly, Applicants respectfully request that the withdrawal of claim 90 be reconsidered, and that claim 90 be examined in the instant application.

### **Summary of Examiner Interview**

Applicants' representative appreciates the courtesies extended by the examiner during the telephonic interview of January 3, 2008. During the interview, Applicants' representative acknowledged that patentability of a product is not proven by pointing out processing differences between the patent application and the prior art. Rather, he explained that process limitations were added to some of the independent claims to rebut the position taken in the Action that the respective processes were the same, and therefore the resulting products must inherently be the same. He cited this statement in the outstanding Action, on page six near the bottom. In response to the position taken in the Action that the limitations in the claims are simply not very limiting (page six of the present Action), Applicants' representative recited the structural limitations present in many of the independent claims:

- (i) that the device comprises at least partially aligned polymer fibers;
- (ii) that the fibers organize themselves into plates of aligned fibers;
- (iii) that there is space between adjacent plates called "fluid planes";
- (iv) that the fluid planes exist as multiple fissures located randomly throughout the structure of the device.

Applicants' representative went on to describe some consequences of these limitations, namely, (i) that fibers in one plate are not necessarily aligned with fibers of another plate; and (ii) that no single plate can extend across the entire dimension of the device, otherwise there would be a non-random single fissure extending across that entire dimension and not multiple fissures located randomly through the device.

The examiner agreed to review Applicants' argument that the respective processes are different. The examiner stated that he would like to see experimental evidence that the Stone and Li structures really *are* different from that of the claimed device.

No agreement was reached regarding the claims.

#### **Claim Rejections – 35 USC §102**

Claims 22-26, 28-33, 38-45, 47-49, 52-53, 61-65, 74-77, 80-81, 84 and 87 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,158,574 to Stone (hereinafter referred to as "Stone"). Claims 22-26, 28-30, 37-48, 52-65, 74-84 and 87 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. US2002/0127270 to Li (hereinafter referred to as "Li"). Applicants respectfully traverse these rejections.

Applicants respectfully submit that neither Stone nor Li discloses or suggests the claimed invention.

Applicants respectfully submit that the claimed invention recites process language to address the Office's position that the references inherently contain the claimed characteristics of the implantable device. Specifically, the claimed method steps clearly differentiate over the device fabrication methods of Stone and Li. More specifically, the claimed implantable device is made by a compressing a fibrous slurry, the compression being (i) without rotation of any piston or mold; and/or (ii) without constraint in directions lateral to the direction of compression. Support for this claim limitation comes from the 5/22/2007 Rule 132 Declaration of co-inventor Timothy Ringeisen, as well as from Figures 2A-2E and 3B of the instant specification.

Stone and Li each disclose rotation as part of their device fabrication process. Li features a rotating mandrel; Stone discloses an embodiment in which the piston or mold rotates during compression so as to align his fibers circumferentially.

Having established that the instant device fabrication method is distinct from those of Stone and Li, Applicants respectfully submit that the burden is shifted back to the Office to show that the respective devices are the same. More particularly, having established that the respective fabrication methods differ, the Office can no longer argue that the respective structures are inherently the same. The Office must re-establish a *prima facie* case of anticipation, Applicants respectfully submit.

Applicants respectfully submit that neither Stone nor Li discloses or suggests the claimed "plates" of independent claims 22, 31, 39 and 42 and their dependents. In his 5/22/07 Declaration, co-inventor Ringeisen states that rotation of the piston or mold such as in Stone will disrupt the plate formation. Further, and to the extent the Action construes the macroscopic layers of Li to be "plates", Applicants respectfully submit that Li neither discloses nor suggests the claimed fluid planes defined by the space between plates, the fluid

planes furthermore existing as **multiple fissures located randomly** within the structure of the device. In contrast, Li seemingly would have but a single fluid plane defined by the laminated layers, or by each pair of laminated layers. Such a fluid plane of Li would not exist as multiple fissures located randomly within the structure, but instead would be a single uniform fluid plane.

Accordingly, these Section 102 rejections should be withdrawn, Applicants respectfully submit.

#### **Claim Rejections – 35 USC §103**

Claims 22-26, 28-33, 36-50, 52-65 and 74-87 were rejected under 35 U.S.C. §103(a) as being unpatentable over Stone in view of Li and further in view of U.S. Patent No. 6,428,576 B1 to Haldimann. Applicants respectfully traverse this rejection.

The Action states that Stone does not disclose a compressed fiber matrix in which the orientation of the fibers within each plate is independent of the orientation of fibers within adjacent plates. The Action furthermore states that Stone does not specifically disclose that the implantable device has any special mechanical properties that would resist tearing from a suture, and that Stone is silent on the use of the membrane as a swellable hemostatic plug, but that it would be obvious that such a device could be used as such. Lastly, the Action states that Stone is silent on the use of plasticizers in the fiber matrix.

The Action turns to Li and Haldiman to supposedly fill in the missing parts. In particular, the Action states that Li discloses a method of fabricating a multiple layer membrane in which the layers are preferably oriented in different directions, and that the biopolymeric fibers possess greater strength due to their orientation. Haldiman is used primarily to show that the use of plasticizers and particulates in implantable bio-polymers being well known.

In response, Applicants respectfully submit that since Li discloses laminating layers in different directions, for example, to enhance strength, this is not independent orientation; this is very deliberate and carefully controlled orientation. "Independent orientation" suggests that adjacent plates having any orientation, even the same orientation is permissible, but to Li, clearly this is not the case. Thus, Li fails to remedy this deficiency in Stone. Haldiman, being directed to plasticizers and particulates in implantable bio-polymers, similarly fails to remedy this deficiency in Stone.

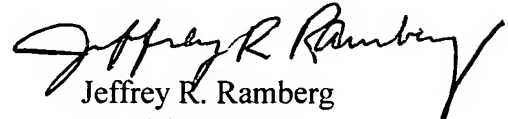
Accordingly, this rejection should be withdrawn.

In view of the amendments and the above remarks, Applicants respectfully submit that the instant application is in condition for allowance. Accordingly, Applicants respectfully request issuance of a Notice of Allowance directed to claims 22-26, 28-33, 36-50, 52-65, 74-87, 90 and 93-94.

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Should the Examiner deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,

  
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